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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,408	12/26/2001	Larry Caldwell	CALD-005	3760
24353	7590	06/29/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			OH, SIMON J	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/029,408	<b>Applicant(s)</b> CALDWELL ET AL.	
	<b>Examiner</b> Simon J. Oh	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's request for continued examination, received on 12 May 2006. Receipt is acknowledged of the applicant's amendment and response, received on 26 May 2006. Receipt is acknowledged of the applicant's affidavit under 37 C.F.R. 1.132, received on 05 June 2006.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For the purpose of advancing prosecution, the examiner will assume that where the claim recites an amount of 1.3%, this is meant to be 1.3% of the mass of the entire dosage form. However, the applicant should make this clear and state this more explicitly.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-18 and 24-28 under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Edwards and Biedermann *et al.* is maintained.

The rejection of Claims 19-23 under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Edwards, Biedermann *et al.*, and Shudo *et al.* is maintained.

Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus (U.S. Patent No. 6,399,093) in view of Edwards (U.S. Patent No. 5,989,559) and Biedermann *et al.* (U.S. Patent No. 5,980,921)

The Petrus patent teaches compositions for the treatment of musculoskeletal disorders, which includes carpal tunnel syndrome (See Abstract; and Column 1, Lines 26-44). Among the suitable active ingredients disclosed are non-steroidal anti-inflammatory agents, such as indomethacin, diclofenac, ibuprofen and ketoprofen (See Column 4, Table 1). The disclosed compositions may be formulated into various dosage forms, including creams and films (See Column 3, Lines 18-25). Such compositions are suitable for treating humans afflicted with musculoskeletal disorders (See Column 13, Examples 3 and 4). Non-steroidal anti-inflammatory agents are typically present in the disclosed formulations in amounts of 5% by weight (See Examples).

The Petrus patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel.

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

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The Biedermann *et al.* patent is used here merely as a teaching reference to point out that diclofenac and indomethacin are known in the art as acetic acid derivatives (See Column 11, Line 66 to Column 12, Line 3).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Petrus and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Petrus. The examiner finds no novelty claim limitations dealing with the specific placement of NSAID formulations on a subject and shifts the burden onto the applicant to demonstrate how the instantly claimed invention shows unexpected results from what is known in the prior art. It is the position of the examiner that topical forms disclosed in the prior art such as films sufficiently read on the instantly claimed invention so as to make the use of patches in treatment obvious to one of ordinary skill in the art.

Regarding the limitations of Claim 30, as the prior art has taught the use of diclofenac, the recitation of its salt, diclofenac epolamine, does not render the claim patentable, absent a showing of criticality by the applicant that the use of this salt leads to unexpected results.

Regarding the limitations of Claim 32, the use of an amount of 1.3% of an NSAID is one that, in the examiner's view, is easily attainable through routine experimentation and

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optimization by one of ordinary skill in the art. Absent a showing of criticality that leads to unexpected results, this claim will not be held to be patentable.

Regarding the limitations of Claim 33, the particular embodiment of a topical formulation is not considered to be patentable, as one of ordinary skill in the art can determine appropriate methods administration. Absent a showing of criticality that leads to unexpected results using this particular dosage form, this claim will not be held to be patentable.

### ***Response to Arguments***

Applicant's arguments filed 26 May 2006 have been fully considered but they are not persuasive. The examiner has considered the affidavit submitted under 37 C.F.R. 1.132, but it is not considered to be persuasive. Although the examiner appreciates the applicant's efforts to shed light on this issue, the affidavit does not negate the plain disclosure of the prior art, because the submitted affidavit still does not establish the term "musculoskeletal disorder" and "entrapment neuropathy" as being entirely mutually exclusive terms as far as they both relate to carpal tunnel syndrome. Therefore, the examiner cannot find the instantly claimed invention to be allowable at this time.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

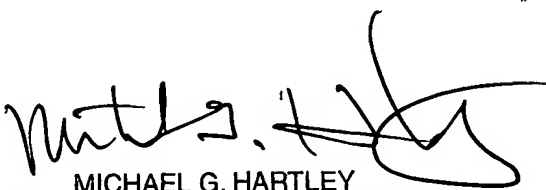
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh  
Examiner  
Art Unit 1618

sj0



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER